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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

KPH HEALTHCARE SERVICES, INC., a/k/a KINNEY DRUGS, INC., individually and on behalf of all others similarly situated, Plaintiff, v. JANSSEN BIOTECH, INC., JANSSEN ONCOLOGY, INC., JANSSEN RESEARCH & DEVELOPMENT, LLC, and BTG INTERNATIONAL LIMITED, Defendants.	Case No. **CLASS ACTION COMPLAINT** DEMAND FOR JURY TRIAL

I. INTRODUCTION

1. Plaintiff KPH Healthcare Services, Inc., a/k/a Kinney Drugs, Inc. ("Plaintiff"), maintaining its principal place of business at 29 East Main Street, Gouverneur, New York 13642, brings this Class Action Complaint on behalf of itself and a putative Class of Direct Purchasers ("Class Members") that purchased Zytiga® ("Zytiga") (abiraterone acetate) during the period from

December 13, 2016 until the anticompetitive effects of Defendants' conduct cease (hereinafter referred to as the "Class Period"). Defendants are Janssen Biotech, Inc., Janssen Oncology, Inc., Janssen Research & Development LLC (collectively, "Janssen") and BTG International Limited ("BTG") (Janssen and BTG are hereinafter referred to together as "Defendants").

2. Plaintiff alleges that Defendants engaged in an unlawful conspiracy to monopolize the market for Zytiga in violation of Sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1, 2.

3. As a result of Defendants' anticompetitive conduct, Plaintiff and Members of a putative Direct Purchaser Class ("Class Members") paid more for Zytiga than they otherwise would have paid in the absence of Defendants' unlawful conduct and sustained damages in the form of overcharges for their Zytiga purchases.

4. Accordingly, Plaintiff, on behalf of itself and Class Members, seeks redress for the overcharge damages sustained as a result of Defendants' antitrust violations. But for Defendants' illegal conduct, Plaintiff and Class Members would not have paid supracompetitive prices for Zytiga.

5. Plaintiff makes the allegations herein based on personal knowledge and investigation of these matters relating to itself, and upon information and belief as to all other matters.

II. NATURE OF THE CASE

6. Zytiga is a prescription drug used in combination with prednisone to treat men with metastatic prostate cancer when surgery and other drugs are not treatment options. Androgens are male hormones that can promote tumor growth in the prostate, and Zytiga works by reducing androgen production in the body. As a potentially critical treatment for prostate cancer, it was reported in 2017 that "[w]ith earlier intervention with Zytiga (abiraterone acetate) the risk of death

was decreased by nearly 40 percent for men with high-risk advanced or metastatic prostate cancer who were newly diagnosed and [had] not yet received hormone therapy, according to findings of two clinical trials presented at the 2017 American Society of Clinical Oncology (ASCO) Annual Meeting."[1]

7. In 1997, Janssen obtained a patent on the compound abiraterone acetate, U.S. Patent No. 5,604,213 (the '213 patent), which expired in December 2016. On April 28, 2011, the FDA approved Janssen's Zytiga, abiraterone acetate tablets, for the treatment of prostate cancer in combination with prednisone. Zytiga was a blockbuster drug for Janssen, and Zytiga has been one of the most profitable drugs sold by Janssen's parent company, Johnson & Johnson. From 2011 to 2012, sales of Zytiga increased from $191 million to $463 million. By 2015, U.S. Zytiga sales exceeded $1 billion.[2]

8. According to a 2016 report, Zytiga was the 17th most expensive drug sold in the U.S., with revenue of more than $2 billion and a typical cost of $15,400 for a 30-day supply.[3] United States sales of Zytiga for the twelve months ending December 31, 2017 were $1.228 billion. The AARP reported in 2017 that Zytiga had a retail price per day of $314.08, which was an 8.7% annual percent change in retail price.[4] According to Janssen's 2017 transparency report, it justified the high price of Zytiga by claiming, "We have an obligation to ensure that the sale of our

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[1] Anita T. Shaffer, *Zytiga Can Be Paradigm-Shifting for Prostate Cancer Treatment* (June 5, 2017), available at https://www.curetoday.com/articles/zytiga-can-be-paradigmshifting-for-prostate-cancer-treatment.

[2] In 2012, its first full year on the market, Zytiga's United States sales had reached $463 million. In 2013, sales reached $750 million. By 2014, sales were $971 million.

[3] Beth Braverman, *The 20 Most Expensive Prescription Drugs in America* (October 17, 2016), available at http://www.thefiscaltimes.com/Media/Slideshow/2016/10/17/10-Most-Expensive-Prescription-Drugs-America?page=3.

[4] *See* AARP Public Policy Institute, *Trends in Retail Prices of Specialty prescription Drugs Widely Used by Older Americans: 2017 Year-End Update*, available at https://www.aarp.org/content/dam/aarp/ppi/2019/06/trends-in-retail-prices-of-specialty-prescription-drugs-year-end-update.doi.10.26419-2Fppi.00073.001.pdf.

medicines provides us with the resources necessary to invest in future research and development."[5] In 2018, United States sales of Zytiga rose to $1.771 billon.[6]

9. From 2007 to 2014, Janssen sought a second patent on a method of using abiraterone acetate in combination with prednisone to treat prostate cancer.

10. It was well known at the time that abiraterone and prednisone could be used to treat prostate cancer. It was also well known that abiraterone works by administering it with a glucocorticoid, a kind of steroid. Prednisone was a commonly used glucocorticoid and had been successfully used in combination with another drug in the same class as abiraterone to treat prostate cancer.

11. The United States Patent and Trademark Office ("PTO") repeatedly rejected Janssen's second patent application, correctly finding that it was obvious to combine abiraterone acetate and prednisone together to treat prostate cancer, and that the claimed invention was therefore not patentable. On five separate occasions, the PTO rejected Janssen's application. The Patent Trial and Appeal Board ("PTAB") and the U.S. District Court for the District of New Jersey, under broad and narrow claim constructions respectively, later reached the same conclusion.

12. In its ongoing effort to obtain the second patent, Janssen argued that the "commercial success" of Zytiga overcame the PTO's finding of obviousness. This argument proved successful, and the PTO issued United States Patent No. 8,822,438 (the '438 patent).

13. However, Janssen had not informed the PTO that the original '213 patent was a "blocking patent," meaning that it covered the only active drug compound in Zytiga. Thus, the

[5] 2017 Janssen U.S. Transparency Report, available at https://jnj-janssen.brightspotcdn.com/b9/96/70c52ba14482a97c48bdfebf0471/2017-janssen-us-transparency-report-march2018.PDF.

[6] *See* Johnson & Johnson Reports 2018 Fourth-Quarter Results, available at http://johnsonandjohnson.gcs-web.com/news-releases/news-release-details/johnson-johnson-reports-2018-fourth-quarter-results.

commercial success of Zytiga was due to the '213 patent preventing other drug companies from making or selling a competing abiraterone acetate product.

14. Janssen and BTG asserted the '438 patent in meritless infringement litigation. The PTAB and the District Court later concluded that the existence of the '213 patent defeated any "commercial success" argument.

15. Defendants' wrongful conduct delayed generic competition by more than one year. As explained herein, but for Defendants' unlawful conduct, generic competition for Zytiga would have entered the market as early as December 2016, and no later than October 2017. Instead, Defendants' unlawful conduct prevented generic manufacturers from entering the market with competing abiraterone acetate products and delayed the entry of additional generic competitors.

III. JURISDICTION AND VENUE

16. This Court has jurisdiction over the subject matter of this action as it arises under Sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1, 2, and Section 4 of the Clayton Act, 15 U.S.C. §§ 15(a). Further, this Court has jurisdiction under 28 U.S.C. §§ 1331, 1337(a).

17. Venue is proper in this District pursuant to 15 U.S.C. §§ 15(a), 22 and 28 U.S.C. § 1391(b) because during the Class Period, Defendants transacted business in the United States, including in this District. Defendants transact business within this District, and the Defendants transact their affairs and carry out interstate trade and commerce, in substantial part, in this district. Further, the Defendants and/or their agents may be found in this District. Defendants' conduct had a direct, substantial, and reasonably foreseeable effect on interstate commerce in the United States, including in this District.

18. This Court has personal jurisdiction over Defendants because, *inter alia*, each Defendant: (a) transacted business throughout the United States, including in this District; (b) had

and maintained substantial contacts with the United States, including in this District; and/or (c) was engaged in an unlawful scheme and conspiracy that was directed at and had the intended effect of causing injury to persons residing in, located in, or doing business throughout the United States, including in this District.

IV. THE PARTIES

A. PLAINTIFF

19. Plaintiff KPH Healthcare Services, Inc. a/k/a Kinney Drugs, Inc. ("KPH") is a corporation organized under the laws of the state of New York, with headquarters in Gouverneur, New York. KPH operates retail and online pharmacies in the Northeast under the name Kinney Drugs, Inc. KPH is the assignee of McKesson Corporation, who directly purchased Zytiga from Defendant Janssen during the Class Period. As a result of Defendant's alleged anticompetitive conduct, KPH paid supracompetitive prices for its Zytiga purchases and was injured by the illegal conduct alleged herein.

B. DEFENDANTS

20. Defendant Janssen Biotech is a corporation organized and existing under the laws of Pennsylvania, with its principal place of business at 800/850 Ridgeview Drive, Horsham, Pennsylvania 19044.

21. Defendant Janssen Oncology Inc. is a corporation organized and existing under the laws of Delaware, with its principal place of business at 10990 Wilshire Blvd., Los Angeles, California 90024.

22. Defendant Janssen R&D is a limited liability company organized and existing under the laws of New Jersey, with its principal place of business at 920 Route 202 South Raritan, New Jersey 08869.

23. Defendant BTG is a company organized and existing under the laws of the United Kingdom, with its principal place of business at 5 Fleet Place, London, EC4M 7RD United Kingdom.

24. Defendants have engaged in the conduct alleged in this Complaint, and/or the Defendants' officers, agents, employees or representatives have engaged in the alleged conduct while actively involved in the management of Defendants' business and affairs.

V. LEGAL AND REGULATORY BACKGROUND

A. The Regulatory Structure for Approval of Generic Drugs and Substitution of Generics for Brand Name Drugs.

25. Under the Federal Food, Drug, and Cosmetic Act ("FDCA"), manufacturers who create a new drug product must obtain the approval of the FDA to sell the new drug by filing a New Drug Application ("NDA"). 21 U.S.C. §§ 301-392. An NDA must include submission of specific data concerning the safety and effectiveness of the drug, as well as any information on applicable patents. 21 U.S.C. §§ 355(a) & (b).

26. When the FDA approves a brand-name manufacturer's NDA, the brand manufacturer may list any patents that the brand manufacturer believes could reasonably be asserted against a generic manufacturer who makes, uses, or sells a generic version of the brand-name drug prior to the expiration of the listed patents in the FDA's book of Approved Drug Products with Therapeutic Equivalence Evaluations, commonly referred to as the "Orange Book." Patents issued after NDA approval may be listed within 30 days of issuance. 21 U.S.C. §§ 355 (b) (1) & (c) (2).

27. A patent applicant is subject to special oaths and duties, such as the duties of disclosure, candor, and good faith, during patent prosecution. A patent applicant is required to disclose to the PTO of "all information known . . . to be material to patentability" including with

respect to prior art. *See* 37 C.F.R. § 1.56. This duty extends to all inventors named on a patent application and any "attorney or agent who prepares or prosecutes the application," as well as "[e]very other person who is substantively involved in the preparation or prosecution of the application." *Id.* § 1.56(c). Where fraud on the PTO "was practiced or attempted" or the duty of disclosure, candor, and good faith "was violated through bad faith or intentional misconduct" no patent should be granted. *Id.* § 1.56(a).

28. The FDA relies completely on the brand-name manufacturer's truthfulness about patents' validity and applicability; the FDA has neither the authority nor the resources to check the manufacturer's representations for accuracy or trustworthiness.

B. The Hatch-Waxman Amendments Advanced the Goal of Providing Access to Generic Pharmaceuticals.

29. The Hatch-Waxman Amendments enacted in 1984 simplified the regulatory hurdles for prospective generic manufacturers by eliminating the need to file lengthy and costly NDAs. *See* Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984). Following passage of the Hatch-Waxman Act, a generic manufacturer seeking approval to sell a generic version of a brand-name drug was permitted to file an Abbreviated New Drug Application (ANDA).

30. An ANDA relies on the scientific findings of safety and effectiveness included in the brand-name drug manufacturer's original NDA, but must show that the generic drug contains the same active ingredient(s), dosage form, route of administration, and strength as the brand-name drug – that is, that the generic drug is bioequivalent to the brand-name drug. The FDA assigns generic drugs that are bioequivalent to branded drugs an "AB" rating.[7]

[7] Generic manufacturers can also seek approval of non-AB-rated generics. The FDCA permits "hybrid" applications that are neither full NDAs containing safety and efficacy data, nor ANDA applications showing that the proposed product is the "same" as the NDA product. 21 U.S.C. § 505(b)(2). Drug products

31. The FDCA and Hatch-Waxman Amendments operate on the presumption that bioequivalent drug products containing identical amounts of the same active ingredients in the same route of administration and dosage form, and meeting applicable standards of strength, quality, purity and identity, are therapeutically equivalent and may be substituted for one another. Thus, bioequivalence demonstrates that the active ingredient of the proposed generic drug would be present in the blood of a patient to the same extent and for the same amount of time as the branded counterpart. 21 U.S.C. § 355(j) (8) (B).

32. Through the Hatch-Waxman Amendments, Congress sought to expedite the entry of generic drugs, thereby reducing healthcare expenses nationwide. Congress also wanted to protect pharmaceutical companies' incentives to create new and innovative products.

33. The Hatch-Waxman Amendments achieved both goals, substantially advancing the rate of generic product launches, and ushering in an era of historic high profit margins for brand name pharmaceutical companies. In 1983, pre-Hatch Waxman Amendments, only 35% of the top-selling drugs with expired patents had generic versions available; by 1998, nearly all did. In 1984, prescription drug revenue for branded and generics totaled $21.6 billion and generic drugs accounted for 18.6% of prescriptions. By 2009, total prescription drug revenue had soared to $300 billion and generic drugs accounted for 75% of prescriptions.

approved under this section use a safe and effective active pharmaceutical ingredient, but modify the drug product in some way so that it differs from the original NDA product, either in dosage form, strength, route of administration, formulation, dosing regimen, or indication. These non-AB-rated generics are not bioequivalent to the innovator product. *See* 21 C.F.R. § 314.54.

C. ANDA Patent Certifications Provide Incentives to Generic Manufacturers to Challenge Patents.

34. To obtain FDA approval of an ANDA, a generic manufacturer must certify that the generic drug addressed in its ANDA will not infringe any patents listed in the Orange Book. Under Hatch-Waxman, a generic manufacturer's ANDA must contain one of four certifications:

i. that no patent for the brand name drug has been filed with the FDA (a "Paragraph I certification");

ii. that the patent for the brand name drug has expired (a "Paragraph II certification");

iii. that the patent for the brand name drug will expire on a particular date and the generic company does not seek to market its generic product before that date (a "Paragraph III certification"); or

iv. that the patent for the brand name drug is invalid or will not be infringed by the generic manufacturer's proposed product (a "Paragraph IV certification").

35. If a generic manufacturer files a Paragraph IV certification, a brand-name manufacturer has the ability to delay FDA approval of an ANDA simply by suing the ANDA applicant for patent infringement. If the brand-name manufacturer initiates a patent infringement action against the generic filer within 45 days of receiving notification of the Paragraph IV certification, the FDA may not grant final approval to the ANDA until the earlier of (a) the passage of 30 months, or (b) the issuance of a decision by a court that the patent is invalid or not infringed by the generic manufacturer's ANDA. The FDA may grant "tentative approval," but cannot authorize the generic manufacturer to go to market.

36. As an incentive to spur generic companies to seek approval of generic alternatives to branded drugs, the first generic manufacturer to file an ANDA containing a Paragraph IV certification gets a period of protection from competition with other generic versions of the drug. For Paragraph IV certifications made prior to December 2003, the first generic applicant is entitled

to 180 days of market exclusivity, *i.e.*, the first approved generic is the only available generic for at least six months.

37. Brand-name manufacturers are incentivized to list patents in the Orange Book due to the high profit margins on brand name drugs and the erosion of those profits due to generic entry. Brand-name manufacturers are motivated to sue any generic competitor that files an ANDA with Paragraph IV certifications even if the generic competitor's product does not actually infringe the listed patent(s) and/or the patent is invalid and unenforceable. As a result, final FDA approval of an ANDA can be delayed for up to 30 months.

D. Generic Competition Serves the Public Interest.

38. Typically, AB-rated generics—generics that meet the FDA's bioequivalence standards—cost much less than their branded counterparts. Over time, as more generic equivalents compete with each other, prices decline even further. Since passage of the Hatch-Waxman Amendments, every state has adopted substitution laws that either require or permit pharmacies to substitute AB-rated generic equivalents for branded prescriptions (unless the prescribing physician has specifically ordered otherwise).

39. Every link in the prescription drug chain has an incentive to choose less-expensive generic equivalents. As a result of federal reimbursement rules and the industry pricing structure, pharmacies typically earn a higher markup on generics. Private health insurers similarly offer direct incentives to pharmacies to substitute cheaper generic products for more expensive branded ones. Health insurers are contractually obligated to pay for the bulk of their members' prescriptions, whether filled with branded or generic drugs, so health insurers offer their members lower copays for generic drugs in order to encourage the use of generics. Members also face the threat of increased health insurance premiums if branded prescription drug costs continue to rise.

40. Once a generic equivalent hits the market, the generic quickly causes sales of the branded drug to diminish. More than 90% of prescriptions for drugs that are available in both branded and generic forms are filled with a generic. The speed with which generic drugs take over the market appears to be increasing: in a sample of drugs losing patent protection between 1991 and 1993, generics on average held a 44% market share after one year; by 2010, IMS industry data reflects that, on average, generics capture 80% of the brand's sales within six months.

41. Because of the strong potential for generics to diminish sales of branded drugs, brand-name manufacturers are motivated to extend their market dominance for as long as possible.

42. Since the passage of the Hatch-Waxman Amendments, every state has adopted laws that either require or permit pharmacies to automatically substitute AB-rated generic equivalents for brand prescriptions (unless the prescribing physician has specifically ordered otherwise). Substitution laws and other institutional features of pharmaceutical distribution and use create the economic dynamic that the launch of AB-rated generics results both in rapid price decline and rapid sales shift from brand to generic purchasing.

43. Experience and economic research demonstrates that the first generic manufacturer to launch prices its product below the price of its brand counterpart.[8] Every state either requires or permits that a prescription written for the brand drug be filled with an AB-rated generic. Thus, the first generic manufacturer almost always captures a large share of sales from the branded drug. At the same time, there is a reduction in average price paid for a prescription for the drug at issue (brand and AB-rated generic combined).

[8] FTC, AUTHORIZED GENERIC DRUGS: SHORT-TERM EFFECTS AND LONG-TERM IMPACT, at ii-iii, (Aug. 2011) ("FTC 2011 AG Study"), *available at* https://www.ftc.gov/sites/default/files/documents/reports/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission.pdf (last accessed June 19, 2018); FTC Pay-for-Delay Study, at 1.

44. During the 180-day exclusivity period, the first filer is the only ANDA-approved generic manufacturer on the market. As recognized by the Supreme Court, it is often the case that most of a first-filer's profits are earned during the 180-day exclusivity period. *See FTC v. Actavis, Inc.*, 570 U.S. 136, 143-44 (2013). Frequently, a brand-name manufacturer has an authorized generic ("AG") on the market during the 180-day exclusivity period. An AG is merely the branded product, manufactured under the brand-name manufacturer's NDA and sold as a generic by the brand-name manufacturer itself, or by a generic manufacturer authorized by the brand-name manufacturer to sell its product. The AG is often sold at a discount compared to the branded product. By marketing an AG, the brand-name manufacturer is able to recoup some of its sales losses caused by the generic entry.

45. If there is no AG on the market during the 180-day exclusivity period, the first-filer prices its product below the branded product, but not as low as if it were facing competition from other generics, including an AG. In these circumstances, the first-filer's product competes only with the brand-name product. And because the brand-name manufacturer rarely drops the branded product's price to match the first-filer, the first-filer does not face the same price competition as when additional generic products—including an AG—are available.

46. Thus, a first-filer charges higher prices and achieves greater sales and profits during the 180-day exclusivity period without an AG on the market. Conversely, an AG product launch during the 180-day exclusivity period can significantly diminish the first-filer's expected profits from its generic launch.

47. Once additional generic competitors enter the market, the competitive process accelerates and multiple generic sellers typically compete vigorously with each other for market share, driving down prices toward marginal manufacturing costs.[9]

48. According to the FDA and the Federal Trade Commission ("FTC"), the greatest price reductions are experienced when the number of generic competitors goes from one to two. In that situation, there are two commodities that compete on price. A typical estimate is that a single generic launch results in a near-term retail price reduction of around 30%, but that two generic entrants can cause a near-term retail price reduction of 50% or more.

49. Soon after generic competition begins, the vast majority of the sales formerly enjoyed by the brand shift to generic sellers. A 2011 FTC Study found that generics captured 80% or more of sales in the first six months.[10] In the end, total payments to the brand-name manufacturer of the drug decline to a small fraction of the amounts paid prior to generic entry. This is so because, although generic drugs are clinically identical to their branded counterparts, they are typically sold at substantial discounts from the brand price. Generic drugs save consumers an estimated $8 to $10 billion a year at retail pharmacies. Billions more are saved when hospitals use generics.

E. Non-Obviousness Under U.S. Patent Law

50. Pursuant to U.S. patent law, "[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title." 35 U.S.C. § 101.

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[9] *See, e.g.*, Patricia Danzon & Li-Wei Chao, *Does Regulation Drive Out Competition in Pharmaceutical Markets?*, J.L. & ECON. (Oct. 2000); Tracy Regan, *Generic Entry, Price Competition, and Market Segmentation in the Prescription Drug Market*, INT'L J.L. INDUS. ORG. (Aug. 2007); R. Frank, *The Ongoing Regulation of Generic Drugs*, NEW ENG. J. MED., v. 357, pp. 1993-96 & n.20 (Nov. 2007).
[10] FTC 2011 AG Study, at 66-67.

51. It is the responsibility of the applicant (and/or the attorney or agent who is prosecuting the application) to accurately explain the invention to the examiner, point out any misunderstandings of or errors made by the examiner, place before the examiner all relevant material and information known to the applicant, and fully and accurately explain the relevance of that material and information to the examiner. That is why applicable regulations impose upon applicants (and their representatives) a duty of candor and good faith in their dealings with the PTO.

52. The PTO processes thousands of patent applications each year. The PTO is overworked, under-funded, and faces massive backlogs. Examiners, on average, spend less than 20 hours reviewing and assessing each application. Most examiners are not lawyers, despite having to assess and respond to legal arguments put before them by the patent applicant's counsel. In reality, the examiner almost always knows less about the invention and technical field than the patent applicant.

53. These conditions are ripe for abuse, particularly where – as in the pharmaceutical industry – patents are a gateway to potentially billions of dollars in sales.

54. Because patents are generally obtained in an *ex parte* setting, with an informational imbalance and no participation by anyone but the applicant and examiner. Compliance with the duty of candor and good faith is essential in preventing improper conduct before the PTO and avoiding the issuance of patents that will not withstand full scrutiny.

55. The duty of candor and good faith is designed to provide the PTO with the information necessary for effective and efficient decision-making. Examiners and other PTO personnel place great reliance on applicants and inventors to fulfill their duty of candor and good faith. Examiners are trained to believe that applicants and their attorneys are complying with that

duty. Generally speaking, the PTO accepts representations from inventors and their attorneys at face value and expects that the duty of candor and good faith is being followed: that there are no half-truths, misleading statements, misrepresentations, or material omissions from inventors and attorneys.

56. The Manual of Patent Examining Procedure reminds attorneys that submission of misleading or inaccurate statements may render the resulting patents unenforceable: "The submission by an applicant of misleading or inaccurate statements of facts during the prosecution of applications for patents has resulted in the patents issuing on such applications being held unenforceable."

F. Patent Validity May Be Challenged.

57. By law, a patent is presumed to be valid. 35 U.S.C. § 282(a). However, patents are routinely invalidated or held unenforceable, either upon reexamination by the PTO, through a review by the PTAB, by court decision, or by jury verdict. A patent can be invalidated for a variety of reasons, including lack of novelty, obviousness, indefiniteness, enablement, or fraud or inequitable conduct.

58. An issued patent may be invalidated if there is a determination that the invention was, in fact, "obvious."

59. A patent claim is invalid as obvious if the purported differences between the subject matter sought to be patented and the prior art are such that the subject matter would have been obvious to a person of ordinary skill in the art (a "POSA"). 35 U.S.C. § 103(a). In other words, if the prior art and the general knowledge of a POSA would be sufficient to teach all the parts of the claim, the patent claim is obvious and generally cannot be allowed.

60. The question of obviousness is resolved on the basis of underlying factual determinations including (1) the scope and content of the prior art, (2) any differences between the

claimed subject matter and the prior art, (3) the level of ordinary skill in that art, and (4) so-called secondary evidence of non-obviousness.

61. A patent applicant can attempt to overcome an obviousness rejection by pointing to "secondary considerations," also referred to as objective indicia of obviousness, such as the commercial success of the claimed invention, a long-felt but unsolved need for the claimed invention, and the failure of others in attempting to make the claimed invention.

62. The law presumes that if an idea were obvious, normal market forces would already have caused a product embodying that idea or claimed invention to be made available (or use of the method of that idea/claimed invention to already be occurring). So if a patent applicant can prove (1) the commercial success of its product embodying the idea or claimed invention and (2) a causal relation, or "nexus," between a product embodying that invention and that success, it may be that the idea or claimed invention was not as obvious as thought; in such instances, the commercial success of the product may be probative on the obviousness inquiry.

63. When others are legally barred from commercially testing the ideas of the newly-claimed invention, though, the commercial or financial success of the product is irrelevant to the obviousness analysis. If the commercial success of the product is due to the fact that no one else can practice the idea or claimed invention, then commercial success arguably says nothing about obviousness.

G. "Blocking" Patents

64. Because the patent right is one to "exclude others from making, using or selling the patented invention," (35 U.S.C. § 154(a)(1)), existing patents can serve to legally bar others from commercially testing an improvement on a claimed invention.

65. If an already-existing patent relates to the general subject matter of a newly-claimed invention and could support a claim of infringement to the newly-claimed invention, the blocking effect of the prior patent must be considered when assessing commercial success.

66. Patents that might be infringed by practice of a later invention are commonly referred to as "blocking patents." The existence of a blocking patent may deter others from investing the resources needed to make, develop, or market a later invention because of the risk of infringement liability and associated monetary and injunctive remedies.

67. Not all prior patents act as blocking patents. For example, a patent covering only a particular formulation of a drug would not prevent another company from selling that drug using a different formulation. Likewise, a patent covering only a particular type of delivery mechanism would not prevent another company from selling the product using a different delivery mechanism. Further, a patent covering only a particular method of using a drug would not prevent another company from selling that drug for a different use.

68. However, if a prior patent covers the underlying product itself, such as a drug compound, it blocks all other potential uses. Without the ability to sell the drug compound itself, there is no motivation to try to develop a new formulation of the drug or a new delivery mechanism or method of use for that drug.

69. The deterrent effect of a blocking patent has no impact on the owner or licensee of the initial patent. So, if the owner or licensee of a drug compound patent wants to seek another, related patent, it can do so without fear of being sued for infringement on the initial patent. Where a later invention is patented by the owner or licensee of an earlier blocking patent, understanding the deterrent effect is relevant to assessing why others may not have pursued the "blocked" invention, and hence, to evaluating any claimed secondary considerations.

70. Courts have made clear that, if all other variables are constant, a blocking patent diminishes possible rewards from a non-owner's or non-licensees' investment activity aimed at an invention whose commercial exploitation would be infringing, thus reducing incentives for innovations in the blocked space by non-owners and non-licensees of the blocking patent.

71. A blocking patent, therefore, can be evidence that discounts the significance of the claim that nobody but the blocking patent's owners or licensees arrived at, developed, and marketed the invention covered by the later patent.

72. Where such a blocking patent exists, commercial success is of "minimal probative value" and is not, by itself, sufficient to justify a finding of non-obviousness. The evaluation of commercial success as a means of overcoming obviousness is a fact-specific inquiry, which should include assessment of the effect of any blocking patents on possible competition.

73. To address the fact that "bad" patents can sometimes slip through and gain approval, patents have long been challengeable in court. More recently, Congress supplemented the litigation route with various administrative remedies, including an *inter partes* review system.

74. In the case of pharmaceutical patents, a generic can prevail in patent infringement litigation by showing that its product does not infringe the patent (and/or that the patent holder cannot meet its burden to prove infringement). It may also, or in the alternative, show that the patent itself is invalid or unenforceable. For example, a patent is invalid or unenforceable when the disclosed invention is obvious in light of prior art. A patent is also invalid or unenforceable when an inventor, an inventor's attorney, or another person involved with the application, with intent to mislead or deceive the PTO, fails to disclose to the PTO material information known to that person to be material, or submits materially false information to the PTO during prosecution.

75. In those circumstances, the PTO's decision to issue a patent does not substitute for a fact-specific assessment of (i) whether the applicant made intentional misrepresentations or omissions on which the PTO relied in issuing the patent, and (ii) whether a reasonable manufacturer in the patent holder's position would have a realistic likelihood of succeeding on the merits of a patent infringement suit.

76. As a statistical matter, if the parties litigate to a decision on the merits, it is more likely that a challenged patent will be found invalid or not infringed than upheld. The FTC reports that generics prevailed in 73% of Hatch-Waxman patent litigation cases resolved on the merits between 1992 and 2002. An empirical study of all substantive decisions rendered in every patent case filed in 2008 and 2009 similarly reports that when a generic challenger stays the course until a decision on the merits, the generic wins 74% of the time.

H. The America Invents Act

77. In 2011, Congress passed the Leahy-Smith America Invents Act ("AIA") to address a widely held concern that invalid patents were being issued and enforced, to the detriment of both innovation and the economy.

78. A centerpiece of the AIA is the system of *inter partes* review. Through this system at the PTO, members of the public can challenge issued patents. The grounds for an *inter partes* review is limited to patentability issues under § 102 (novelty) or § 103 (obviousness); even then, the challenge can only be based on prior art consisting of patents or prior publications.

79. The advent of *inter partes* review created a less expensive and more efficient venue for patent validity challenges than challenges in district court. *Inter partes* review proceedings are overseen by technically educated judges, skilled in the sciences of a particular proceeding.

80. An *inter partes* review commences when a party – often an alleged patent infringer – petitions the PTAB to reconsider the PTO's issuance of an existing patent and invalidate it on the ground that it was obvious or anticipated by prior art.

81. The PTAB will grant a request for an *inter partes* review only if the challenger of the patent shows "a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition."[11] The PTAB must conclude the review within one year of the institution date.

82. Once commenced, the review proceeds before the PTAB in much the same way as standard litigation. The parties conduct discovery, file briefs, and engage in oral argument.

83. The PTAB proceedings have become an effective method of challenging improperly granted patents: only 4% of all Board petitions end with a final written decision in which all claims are upheld as patentable; 69% of all PTAB petitions that have reached final written decisions have led to findings that all of the patents' claims were unpatentable.

VI. FACTUAL ALLEGATIONS

A. The Development of Abiraterone Acetate

84. Prostate cancer results from the uncontrolled growth of abnormal cells in the prostate gland. Once a prostate cancer tumor develops, androgens such as testosterone promote prostate cancer growth. In its early stages, localized prostate cancer is often curable with local therapy including, for example, surgical removal of the prostate gland and radiotherapy. When local therapy fails, the disease progresses into metastatic cancer. Local therapy fails in up to one third of men with localized prostate cancer.

[11] 35 U.S.C. § 314(a).

85. The enzyme 17α-hydroxylase/$C_{17, 20}$-lyase ("CYP17") is involved in testosterone synthesis, and CYP17 inhibitors have for decades been known to be useful in the treatment of cancer, specifically androgen-dependent disorders like prostate cancer.

86. Abiraterone acetate, a prodrug of abiraterone, is a CYP17 inhibitor, and considered a second-line therapy for the treatment of prostate cancer. A prodrug is a biologically inactive compound that the body can metabolize to produce a drug.

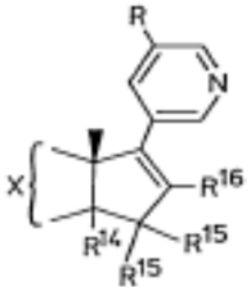
87. Abiraterone was first discovered in the early 1990s by a group of scientists at the Institute of Cancer Research ("ICR"). Those scientists were familiar with promising research from the 1980s involving ketoconazole, another CYP17 inhibitor, and they set about making a drug molecule that could mimic some of the properties of ketaconazole.

88. Before the '438 patent's 2006 priority date, scientists in the field knew that androgen hormones such as testosterone promote prostate cancer growth and therapies aimed at suppressing androgen production were a mainstay of prostate cancer treatment. "First line" treatments such as surgical or chemical castration could eliminate most androgen production, but residual androgen produced by adrenal glands could eventually support cancer growth. By the 1990s, researchers knew that CYP17 inhibitors, such as abiraterone and ketoconazole, effectively suppressed both testicular and adrenal androgen production.[12] Abiraterone was recognized as being especially selective and potent. Scientists also recognized that since CYP17 inhibitors suppressed synthesis of beneficial adrenal hormones, concomitant administration of a replacement glucocorticoid was likely necessary. Synthetic glucocorticoids such as prednisone had been used for palliative effects in treating refractory prostate cancer since the 1950s[13], and a 1998 study

[12] *See, e.g.*, Pont, A., Williams, P.L., Azhar, S., Reitz, R.E., Bochra, C., Smith, E.R., Stevens, D.A., *Ketoconazole blocks testosterone synthesis*, *ARCH INTERN MED.*, 142(12):2137-40 (Nov. 1982).
[13] *See, e.g.*, Lin, K., Wang, L., *New dimensions of glucocorticoids in cancer treatment*, STEROIDS, 111:84-88 (2016).

showed other anti-prostate cancer activity associated with prednisone.[14] This long-standing knowledge is undisputed.

89. On September 30, 1994, scientists, including Susan E. Barrie, Michael Jarman, Gerard A. Potter, and Ian R. Hardcastle, filed Patent Application No. 08/315,882, covering the class of compounds to which abiraterone acetate belongs. As the patent's specification described, the "invention relates to 7-substituted steroids and their use in the treatment of androgen-dependent and oestrogen-dependent disorders, especially prostatic cancer and breast cancer respectively." The claimed invention related to drug compounds having the following general formula:



90. After a series of rejections, the inventors convinced the PTO that one particular feature of the claimed compounds (a mandatory double bond at the 16, 17 position and position 14 can only be substituted with halogen or C_{1-4}alkyl) was sufficiently non-obvious so as to warrant patentability.

91. On February 18, 1997, the PTO issued this application as U.S. Patent No. 5,604,213 (the '213 patent or the '213 blocking patent), assigned to British Technology Group Limited.

[14] *See, e.g.*, Zoorob, R., Cender, D., *A different look at corticosteroids*, AM. FAM. PHYSICIAN, 58(2):443-450 (Aug. 1, 1998).

92. In 2004, Cougar Biotechnology obtained an exclusive license to the '213 patent from British Technology Group. Janssen acquired Cougar Biotechnology in May 2009.

B. Janssen's Applications for a Second Patent Are Rejected as Obvious.

93. On August 24, 2007, Cougar, through two of its scientists, filed patent application number 11/844,440 (the '440 application), listing 36 claims.

94. On December 29, 2009, following Janssen's acquisition of Cougar, PTO examiner San-ming Hui noted that claims 1-26 were drawn to a method of treating cancer, while claims 27-36 were directed to a composition for the treatment of cancer. When an application claims two or more distinct inventions, the Patent Act, 35 U.S.C. § 121, permits the PTO to require the applicant to restrict the application to one of the inventions. Examiner Hui required Janssen to choose between its method claims and composition claims.

95. In response, Janssen cancelled claims 1-36 and submitted new claims 37-63 relating to a "method for the treatment of a prostate cancer in a human comprising administering to said human a therapeutically effective amount of abiraterone acetate or a pharmaceutically acceptable salt thereof and a therapeutically effective amount of prednisone" (claim 37), a "method for the treatment of a refractory prostate cancer in a human comprising administering to said human a therapeutically effective amount of abiraterone acetate or a pharmaceutically acceptable salt thereof and a therapeutically effective amount of prednisone" (claim 48), and various dependent claims deriving from claims 37 & 48.

96. On April 8, 2010, examiner Hui issued her first rejection of claims 37-63 as being unpatentable over two pieces of prior art. Specifically, examiner Hu found that a 2004 article by A. O'Donnell on the results of clinical trials of abiraterone (2004)[15] teaches (a) abiraterone acetate

[15] A. O'Donnell, et al., "Hormonal Impact of the 17α-hydroxylase/$C_{17,20}$-lyase Inhibitor Abiraterone Acetate (CB7630) in Patients with Prostate Cancer" (O'Donnell 2004).

is a known CYP17 inhibitor, which can be used to suppress testosterone level in prostate cancer patients, (b) 800 mg of abiraterone acetate is useful in suppressing the serum testosterone level, and (c) concomitant glucocorticoid therapy may be needed for continuous use of abiraterone acetate. Hui also found that a 1996 article by IF Tannock *et al.*[16] "teaches 10 mg of prednisone in combination with other anti-cancer drugs as effective in treating refractory hormonal-resistant prostate cancer." Thus, it would have been obvious to one skilled in the art to employ both abiraterone acetate and prednisone to treat prostate cancer including refractory prostate cancer, and the motivation to do so would have been present, since abiraterone acetate provided a new mechanism of action in treating prostate cancer.

97. On July 8, 2010, Janssen submitted its response to examiner Hui's rejection and claimed the following:

a. Neither O'Donnell (2004) nor Tannock (1996) discloses using abiraterone acetate and prednisone together for the treatment of prostate cancer;

b. Neither O'Donnell (2004) nor Tannock (1996) provide any reason to modify their teachings to arrive at a method of treating prostate cancer with a combination of abiraterone acetate and prednisone;

c. The patients in the O'Donnell (2004) study were not allowed to take concomitant steroids (and, thus O'Donnell (2004) actually teaches away from the co-administration of steroids);

d. O'Donnell (2004) concludes that abiraterone acetate is potentially useful in causing reductions in testosterone levels and is thus potentially useful as a second-line treatment of patients who have become refractory to gonadotrophin-releasing hormone agonists;

e. There are no disclosures of prednisone in O'Donnell (2004) and no suggestion to modify its administration of abiraterone acetate to also administer prednisone;

f. O'Donnell (2004) concludes that it is unknown whether or not it might be useful to administer a glucocorticoid with abiraterone acetate, and that further study is needed, thus, at most O'Donnell (2004) provides an invitation to experiment;

[16] IF Tannock, et al., "Chemotherapy with mitoxantrone plus prednisone or prednisone alone for symptomatic hormone-resistant prostate cancer" J. Clin. Oncol., 1996; 14:1756-1764 (Tannock 1996).

g. Tannock (1996) discloses the results of a study concerning whether chemotherapy using mitoxantrone, along with prednisone, provides a better palliative response than prednisone (and showed no significant difference in survival rates);

h. Tannock (1996) chose mitoxantrone for specific reasons and there is no suggestion of using another drug, including abiraterone acetate, especially since abiraterone acetate and mitoxantrone are two different types of drugs; and

i. Neither O'Donnell (2004) nor Tannock (1996) identified a "problem" in using abiraterone acetate without prednisone or vice-versa.

98. Janssen also made an "unexpected results" argument, pointing to a newly published article by Danila *et al.*[17] on a clinical study of patients with progressive metastatic castration-resistant prostate cancer who were administered abiraterone acetate together with prednisone. Janssen argued that the results of Danila 2010 unexpectedly showed: (a) abiraterone acetate and prednisone resulted in antitumor effects; (b) a decline in the levels of prostate- specific-antigen, demonstrating antitumor activity; (c) a potential for reversing clinical resistance to abiraterone acetate; and (d) a lowered incidence of mineralocorticoid-related toxicities.

99. On September 24, 2010, examiner Hui again rejected claims 37-63. Hui rejected Janssen's lack of motivation to combine argument, noting that the initial rejection "resides in the fact that both the herein agents are known to be useful in treating prostate cancer. Since abiraterone acetate provide[s] a new mechanism of action in treating prostate cancer and prednisone is known to be useful in treating refractory prostate cancer, concomitant employment of both compounds into a single method useful for the very same purpose, treating prostate cancer, would be considered *prima facie* obvious."

[17] Danila *et al*. "Phase II Multicenter Study of Abiraterone Acetate Plus Prednisone Therapy in Patients with Docetaxel-Treated Castration-Resistant Prostate Cancer," *J. Clin. Oncol.* Vol. 28, no. 9, pp. 1496-1501 (March 20, 2010) (Danila 2010).

100. Hui rejected Janssen's teaching away argument, noting that O'Donnell (2004) was trying to determine the effects of abiraterone acetate, and thus it would have been improper to administer another drug that has an endocrine effect, such as steroids, to the patients.

101. Hui also rejected Janssen's unexpected results arguments, noting that the claimed unexpected results were not "commensurate with the scope of the subject matter recited in the claims."

102. Janssen made no further attempts to support the claims in the '440 application, and the PTO issued a notice of abandonment as to the '440 application.

C. Janssen Obtains FDA Approval to Sell Abiraterone Acetate.

103. On December 18, 2010, Janssen filed an NDA seeking FDA approval to sell tablets containing abiraterone acetate, bearing the trade name Zytiga.[18]

104. On April 28, 2011, the FDA approved Janssen's NDA for the sale of Zytiga. Following approval of the NDA, Janssen submitted the '213 patent for listing in the FDA's Orange Book as covering Zytiga. The recommended dose of Zytiga is 1000 mg (either two 500 mg film-coated tablets, or four 250 mg uncoated tablets) to be taken orally once daily, along with 5 mg of prednisone to be taken twice daily. The active ingredient in Zytiga tablets consists of non-micronized abiraterone acetate.

D. The PTO Rejects Janssen's Subsequent Patent Applications Three Times.

105. While awaiting FDA approval of Zytiga, Janssen had renewed attempts to obtain a second patent. On February 24, 2011, Janssen scientists filed Patent Application No. 13/034,340

[18] The NDA was initially filed by Ortho Biotech Oncoloft Research and Development, a unit of Cougar Biotechnology, Inc.

(the ’340 application), identifying it as a continuation of the ’440 application, and re-asserting the same 36 claims originally set out in the ’440 application.[19]

106. As she had with the earlier ’440 application, examiner Hui determined that the ’340 application actually claimed two distinct inventions and required Janssen to choose between its method claims and composition claims. Janssen again elected to prosecute the method claims rather than the composition claims for the ‘340 application.

107. On December 21, 2011, Janssen cancelled all 36 claims in the ’340 application and proposed 20 new method claims, numbered 37-56. The new claims were directed to “[a] method for the treatment of a prostate cancer in a human comprising administering to said human a therapeutically effective amount of abiraterone acetate or a pharmaceutically acceptable salt thereof and a therapeutically effective amount of prednisone.”

108. On February 3, 2012, examiner Hui rejected the patent in its entirety, finding the newly-proposed claims obvious in light of O’Donnell (2004) and Tannock (1996).

109. Examiner Hui again explained that O’Donnell (2004) “teaches abiraterone acetate is known to be an inhibitor of 17ahydroxylase/C17,20-lyase, which can be used to suppress testosterone level in prostate cancer patients” and “teaches 800 mg of abiraterone acetate as useful in suppressing the serum testosterone level.” And as before, examiner Hui further noted that O’Donnell (2004) “also teaches that concomitant glucocorticoid therapy may be needed for continuous use of abiraterone acetate.”

[19] This application was a continuation of U.S. Patent Application No. 11/844,440, filed on August 24, 2007, and claimed the priority date of provisional U.S. Patent Application No. 60/921,506, filed on August 25, 2006. Both were filed by Cougar, on assignment from its scientists Auerbach and Belldegrun; Cougar, at that point, was owned by Johnson & Johnson. Going forward, this patent application is referred to as Janssen’s.

110. While examiner Hui recognized that O'Donnell (2004) did "not expressly teach the use of [the steroid] prednisone in the method of treating prostate cancer" and did not "expressly teach the use of the herein claimed dosage and regimen for prednisone and abiraterone acetate," she again noted that Tannock (1996) did just that: "Tannock et al. teaches 10 mg of prednisone in combination with other an[ti]-cancer drug as effective in treating refractory hormonal-resistance prostate cancer."

111. Combining these two prior art references, examiner Hui concluded that "[i]t would have been obvious to one of ordinary skill in the art at the time the invention was made to employ both prednisone and abiraterone acetate, in the dosage herein claimed, together in a method of treating prostate cancer, including refractory prostate cancer."

> Since abiraterone acetate provide a new mechanism of action in treating prostate cancer and prednisone is known to be useful in treating refractory prostate cancer, concomitant employment of both compounds into a single method useful for the very same purpose, tre[a]ting prostate cancer, would be considered prima facie obvious (See In re Kerkhoven 205 USPQ 1069 (CCPA 1980)). Treating refractory prostate cancer with abiraterone acetate would be reasonably expected to be effective since abiraterone provides a new mechanism of action against prostate cancer. O'Donnell et al. provides an additional motivation to concomitantly employ prednisone since employing replacement glucocorticoid such as prednisone would ensure the safety and effectiveness of abiraterone acetate.

112. Examiner Hui further explained that the "the optimization of result effect parameters (e.g., dosage range, dosing regimens) is obvious as being within the skill of the artisan. The optimization of known effective amounts of known active agents to be administered is considered well in the competence level of an ordinary skilled artisan in pharmaceutical science, involving merely routine skill in the art."[20]

[20] In addition to her obviousness rejection, the examiner provisionally rejected claims 37-56 of the '340 Application for non-statutory double patenting based on Janssen's co-pending Patent Application No. 12/898,149 (the '149 application). In plain English, the '340 was duplicative of another Janssen patent application. Because the PTO had not yet issued a patent based on the '149 application at the time of the examiner's rejection, the examiner clarified that her double patenting rejection was only provisional: it

113. Approximately five months after receiving the PTO's third rejection, Janssen responded on July 3, 2012, acknowledging the two prior art references, but arguing that O'Donnell (2004) and Tannock (1996) only "suggest that the combination of abiraterone acetate and prednisone would be obvious to try." According to Janssen, "[n]othing in the art teaches or suggests that abiraterone acetate in combination with prednisone would be a particularly useful combination for cancer treatment."

114. Janssen also asserted that two secondary considerations of non-obviousness enabled it to traverse the examiner's prima facie obviousness rejection: unexpected results and commercial success.

115. First, Janssen contended that "the claimed invention produces unexpected results." To support this argument, Janssen referenced a 2011 study published in *Nature Reviews Clinical Oncology* that found that Janssen's claimed invention successfully lowered the pain associated with abiraterone treatment and reduced a certain type of tumor cell. Janssen urged that "the claimed invention produces the unexpected results of increased survival, reduced pain, and lower levels of a biomarker connected with survival."

116. Second, Janssen claimed that its "invention has experienced an impressive commercial success." Contending that Zytiga is a commercial embodiment of the claimed invention approved for sale in the U.S. in April 2011, Janssen emphasized that "[w]ithin the first year of release, worldwide sales were over $400 million." Thus, according to Janssen, "not only did the claimed invention enjoy immediate commercial success, this commercial success grew over the first year of commercial availability."

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would only take effect if the PTO issued a patent based on the '149 application. Janssen informed examiner Hui on July 3, 2012 that it had abandoned the '149 application.

117. On September 11, 2012, examiner Hui issued a final office action rejecting both of Janssen's arguments on secondary considerations. Hui found Janssen's unexpected results to be "unpersuasive", and "[b]ecause abiraterone and prednisone are known to be individually effective in treating prostate cancer," their "additive effective is expected."

118. With respect to Janssen's commercial success argument, Examiner Hui noted that "gross sales figures do not show commercial success absent evidence as to market share, or as to the time period during which the product was sold, or as to what sales would normally be expected in the market." Further, "[i]n the instant case, . . . no evidence of commercial success was provided."

119. Janssen requested on January 11, 2013 that the examiner reconsider her final action and cited a new reference, an article published in the *New England Journal of Medicine,* in support of its unexpected results argument. Janssen made no new arguments regarding Zytiga's commercial success. Examiner Hui found Janssen's argument unpersuasive. On March 4, 2013, Hui issued another final rejection of all of Janssen's arguments as they pertained to claimed "unexpected results." Examiner Hui again noted that as "abiraterone and prednisone are known to be individually effective in treating prostate cancer," an "at least additive effective is expected."

120. In light of the '213 patent's looming expiration date of February 18, 2014, BTG filed an application for a patent term extension on the '213 patent on June 22, 2011. A patent term extension is intended to compensate a patent applicant for delays occurring during the prosecution of the patent before the PTO. An application for a term extension must be filed within 60 days of the regulatory approval of the product, and at least one claim of the patent must cover the product or a method of using the product.

121. In its application for a patent term extension, BTG noted that the FDA "has approved New Drug Application ("NDA") No. 202379 for ZYTIGA (abiraterone acetate). The active ingredient of ZYTIGA is abiraterone acetate." BTG also represented that the '213 patent "claims the active ingredient of the approved product which is abiraterone acetate."

122. On September 25, 2013, examiner Bottino (the examiner who handled the original application for the '213 patent) granted a patent term extension for the '213 patent. The PTO determined, based on the representations made by BTG, that since the claims of the '213 patent "cover the human drug product ZYTIGA (abiraterone acetate)," an extension of 1,029 days was warranted. The expiration of the '213 blocking patent was set at December 13, 2016, granting BTG, and its licensee Janssen, an additional 1,029 days, or nearly three years, of patent life.

E. Janssen Fails to Disclose Information to the PTO and Obtains the '438 Patent.

123. On June 4, 2013, Janssen submitted a new response, re-asserting Zytiga's commercial success as grounds for patentability. Janssen provided the FDA-approved label for Zytiga, along with a December 2012 FDA News Release noting that the agency had decided to expand Zytiga's use for late-stage prostate cancer. Additionally, Janssen submitted two news releases from the FDA (dated June 17, 2010 and August 31, 2012) and a Janssen slideshow, dated May 2013.

124. Janssen claimed that these references showed that Zytiga was a market leader with both chemo-refractory prostate cancer patients (patients who have previously received chemotherapy treatment) and chemo-naive prostate cancer patients (patients who have not previously received chemotherapy treatment). Janssen emphasized Zytiga's success over two other cancer treatments: Jevtana, which the FDA approved a year before Zytiga, and Xtandi, which the FDA approved a year-and-a-half after Zytiga.

125. At no time during the patent prosecution did Janssen inform examiner Hui that the '213 blocking patent prevented any other company from even trying to bring an abiraterone acetate product to the market. Janssen intentionally and deliberately refrained from mentioning the '213 blocking patent when pressing its commercial success argument because it knew that the existence of such a blocking patent would render its purported evidence of commercial success to be of minimal, if any, probative value.

126. Based on Janssen's new arguments and the limited evidence Janssen put before her, examiner Hui reversed course and issued a notice of allowance to Janssen on July 3, 2013. In support of this allowance, the examiner provided a single justification: "The unexpected commercial success of the launch of the drug obviates the rejection under 35 U.S.C. § 103(a)."

127. As issued, claim 1 of the '438 patent recites:

> A method for the treatment of a prostate cancer in a human comprising administering to said human a therapeutically effective amount of abiraterone acetate or a pharmaceutically acceptable salt thereof and a therapeutically effective amount of prednisone.

128. After receiving the notice of allowance, Janssen began filing dozens of additional references. On October 3, 2013, Janssen disclosed 25 prior art references, all of which were "Other Prior Art – Non Patent Literature Documents." On October 25, 2013, the examiner maintained her allowance for "the same reasons of allowance as previous[ly] communicated in the previous notice of allowance."

129. On January 10, 2014, Janssen disclosed twelve more references in a second information disclosure statement, again putting them all in the "Other Prior Art – Non Patent Literature Documents" category. On February 11, 2014, the examiner accepted them without comment and maintained her allowance because "[t]he commercial success of the combination of prednisone and abiraterone to treat prostate cancer obviate the rejection under 35 USC 103(a)."

130. On May 9, 2014, Janssen submitted a third information disclosure statement containing 29 more references. As before, most (26) of these references were non-patent literature documents, although this submission also contained three patent-related documents. One was an abandoned United States patent application (20060030608) for anti-aromatase compounds and two were foreign patent references (EP2478907, the European counterpart to the '340 application and WO2006027266, relating to site and time controlled release mechanisms). These three patent-related references would be the only ones cited in the '438 patent.

131. In addition to these references, Janssen disclosed "the existence of commonly owned pending U.S. Patent Application Serial Nos. 11/844,440." Janssen notified the examiner that the '440 application had been "published and is therefore publicly available in PAIR. Moreover, the Patent Office has issued one or more Office Actions in this application." Janssen "invited" the examiner "to review the prosecution of this application to determine its impact, if any, on the prosecution of the present application." However, although Janssen had already submitted over 50 new references, post-allowance, to the PTO, Janssen did not submit a copy of the '440 application, claiming that it did not want to "overwhelm the Examiner with an overly large IDS." Janssen also did not mention that the '440 application had been declared abandoned more than three years earlier, on April 14, 2011.

132. On May 30, 2014, Janssen submitted a fourth information disclosure statement containing eight new references. Again, Janssen made no mention of the '213 blocking patent.

133. On June 2, 2014, the examiner again affirmed her allowance and the sole reason given as "[t]he commercial success of the combination of prednisone and abiraterone to treat prostate cancer obviate the rejection under 35 USC 103(a)."

134. On June 16, 2014, Janssen made its final submission, along with eight more non-patent references. Still absent from the references supplied to the PTO was the '213 blocking patent. On August 13, 2014, the PTO issued notice of a projected patent number and issue date.

135. On September 2, 2014, the '340 application issued as U.S. Patent No. 8,822,438 (the '438 patent), claiming "methods for treating cancer" comprising "administ[ration of] a 17c-hydroxylase/Czo-lyase inhibitor, such as abiraterone acetate, in combination with at least one additional therapeutic agent such as an anti-cancer agent or a steroid." The patent's twenty approved claims all specify use of abiraterone acetate and prednisone.

136. The '213 blocking patent was not cited to the PTO during the prosecution of the '438 patent, and it does not appear in the References Cited portion of the '438 patent.

137. Subsequent to the issuance of the '438 patent, there was a proceeding to correct inventorship in which Dr. Johann S. de Bono was added as an inventor to the '438 patent. BTG is the owner of Dr. de Bono's inventions and thus asserts co-ownership of the '438 patent along with Janssen.

F. In 2015, Generic Competitors Begin Attempting to Enter the Market.

138. On April 28, 2015, multiple generic companies submitted ANDAs seeking FDA approval to launch generic Zytiga. Based on publicly-available FDA approval letters, at least five generic companies filed on this date.

139. These generic ANDA filers promptly provided notice to Janssen of their ANDA filings and Paragraph IV ("P.IV") certifications:

Generic company	Notice letter date	P.IV on '213 patent?	P.IV on '438 patent?
Actavis	June 22, 2015	Yes[21]	Yes
Amneal	July 10, 2015	No	Yes
Apotex	July 7, 2015	No	Yes
Citron	June 25, 2015	No	Yes
Dr. Reddy's	July 9, 2015	No	Yes
Mylan	July 9, 2015	No	Yes
Par	June 26, 2015	No	Yes
Sun	June 25, 2015	No	Yes
Teva	July 7, 2015	No	Yes
Hikma/West Ward	June 24, 2015	No	Yes
Wockhardt	June 24, 2015	No	Yes

140. On July 31, 2015, Janssen and BTG filed a single lawsuit against eleven generic companies in the District of New Jersey.[22] The case was assigned to Judge Kevin McNulty. The filing of this lawsuit triggered the Hatch-Waxman 30-month stay as to the approval of each of their Zytiga ANDAs, a stay that would be extended a year to October 27, 2018 because of Zytiga's NCE exclusivity.[23]

141. Of the eleven different generic companies named by Janssen in a single lawsuit, only one of them, Actavis, had submitted a Paragraph IV certification as to the '213 blocking patent. That is, ten of the eleven defendants made clear that they did not intend to sell generic abiraterone acetate until at least December 13, 2016, when the '213 blocking patent expired. As

[21] Actavis, the only ANDA filer who submitted a P.IV certification on the '213 blocking patent, subsequently changed that to a Paragraph III certification and stipulated with Janssen that it would not seek to sell generic Zytiga prior to the patent's expiration on December 13, 2016.

[22] *See BTG International Ltd., et al., v. Amneal Pharmaceuticals LLC, et al.*, 15-cv-5909 (D.N.J.).

[23] Due to the NCE exclusivity provisions discussed above, the "30-month stay" as to the '438 patent actually lasted until October 27, 2018.

to those ten generic defendants, the only patent that could give Janssen the protection afforded by the 30- month stay was the '438 patent.

142. Consequently, after the '213 patent expired, the 30-month stay remained in effect only because of Janssen's strategic and unlawful decision to continue prosecuting its case as to the '438 patent, which Janssen knew to be invalid.

143. Janssen's decision to sue all of the generic ANDA filers in a single lawsuit asserting both the '213 and '438 patent does not change the sham nature of the claims it initially asserted against the ten generic manufacturers who had not served Paragraph IV certifications as to the '213 patent. Nor does it insulate the sham nature of the claims it later maintained against all eleven generic manufacturers after the expiration of the '213 patent.

144. On December 4, 2015, Amerigen Pharmaceuticals Limited (Amerigen) filed a petition for *inter partes* review of the '438 patent with the PTAB. Amerigen requested cancellation of all 20 claims of the '438 patent, arguing that (a) claims 1-20 were obvious over O'Donnell (2004) in view of a 1990 article by G.S. Gerber and G.W. Chodak,[24] and (b) claims 1- 4 and 6-11 were obvious over the '213 patent in view of Gerber (1990).

145. Amerigen pointed out that the claimed invention of the '438 patent was, as the PTO held, obvious. Further, the prior art taught the use of abiraterone acetate as an effective anti-cancer agent which suppresses testosterone synthesis in prostate cancer patients. And while it was known that suppressing testosterone synthesis was beneficial to treating prostate cancer, it was also known that using a CYP17 inhibitor to reduce testosterone synthesis also undesirably suppressed the production of cortisol, a glucocorticoid. So, the prior art taught that concomitant glucocorticoid

[24] Gerber, G.S. & Chodak, G.W., *Prostate specific antigen for assessing response to ketoconazole and prednisone in patients with hormone refractory metastatic prostate cancer*, 144 J. Urol. 1177-79 (1990) (Gerber 1990).

replacement therapy might be necessary when administering abiraterone acetate, which was a common practice when administering ketoconazole, another CYP17 inhibitor. The prior art also taught that abiraterone acetate was a more effective CYP17 inhibitor than ketoconazole. Finally, the prior art taught that the combination of ketoconazole and prednisone was a safe and effective treatment for refractory metastatic prostate cancer.

146. Amerigen noted that based on the teachings of prior publications including the '213 blocking patent, a POSA would have combined abiraterone acetate and prednisone with a reasonable expectation of success.

147. Amerigen went on to explain why "secondary considerations" were insufficient to overcome that finding. In particular, Amerigen pointed out that evidence of secondary considerations, such as commercial success, is only relevant if the patentee can show a direct link, or "nexus," between the secondary consideration and the claims of the patent. But any commercial success of Zytiga was due to the effectiveness of abiraterone acetate in treating prostate cancer, not the subject matter of the '438 patent (*i.e.*, the combination of abiraterone acetate and prednisone).

148. Amerigen noted that Janssen had presented zero evidence to the PTO suggesting that it was the claimed invention, rather than abiraterone acetate itself, that was responsible for any commercial success. "Instead, [Janssen] mislead the Examiner by arguing that because Zytiga is approved in combination with prednisone, Zytiga is a commercial embodiment of the claimed invention."

149. Amerigen pointed to Janssen's failure to provide any evidence of unexpected results or to any showing that the claimed invention satisfied any long-felt but unmet need.

150. Finally, Amerigen pointed out that both abiraterone acetate and its use for the treatment of cancer are claimed in the '213 patent and the existence of this "blocking patent" acted to limit the ability of any would-be competitors to develop a competing product.

G. The PTAB Accepts Amerigen's IPR Petition in 2016.

151. On May 31, 2016, the PTAB granted Amerigen's petition and instituted a formal proceeding to examine the '438 patent. The PTAB grants petitions for *inter partes* review only where the challenger of the patent shows "a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition."[25]

152. In so doing, the PTAB adopted Janssen's lexicography and interpreted certain claims terms:

Claim term(s)	**PTAB construction**
"treat," "treating," and "treatment"	include the eradication, removal, modification, management or control of a tumor or primary, regional, or metastatic cancer cells or tissue and the minimization or delay of the spread of cancer
"anti-cancer agent"	any therapeutic agent that directly or indirectly kills cancer cells or directly or indirectly prohibits, stops or reduces the proliferation of cancer cells
"refractory cancer"	cancer that is not responding to an anticancer treatment or cancer that is not responding sufficiently to an anti-cancer treatment

153. In finding a reasonable likelihood that Amerigen would prevail on obviousness, the PTAB noted that O'Donnell (2004) suggests the co-administration of a glucocorticoid (such as prednisone), Gerber (1990) discloses co-administration of prednisone with ketoconazole, and ketoconazole and abiraterone acetate were both known CYP17 inhibitors. Likewise, the PTAB noted that the '213 patent (sometimes referred to in the PTAB proceedings as Barrie (2004))

[25] 35 U.S.C. § 314(a).

discloses the use of abiraterone acetate for treating prostate cancer and contrasts that with the performance of ketoconazole.

154. On June 29, 2016, Argentum sought *inter partes* review of the '438 patent. Concurrently with its petition, Argentum filed a motion seeking to join its case with the one filed by Amerigen.[26] The Amerigen and Argentum petitions were eventually consolidated.

155. On June 30, 2016, Mylan sought *inter partes* review of the '438 patent, raising many of the same points that had been made by Amerigen, and seeking cancellation on the same grounds (obviousness over O'Donnell (2004) in view of Gerber (1990) and obviousness over the '213 patent in view of Gerber (1990)). Shortly thereafter, a group of petitioners including Actavis, Amneal, Dr. Reddy's, Sun, Teva, West-Ward, and Hikma filed a petition on the same grounds, and sought joinder with the Mylan IPR. A few months later, Wockhardt filed an *inter partes* review petition also challenging the '438 patent.

156. All of these petitions raised the same basic arguments that had been raised in the Amerigen petition, and all were later accepted by the PTAB.

157. On August 30, 2016, Actavis, Janssen, and BTG filed a joint stipulation indicating that Actavis had changed its Paragraph IV certification on the '213 blocking patent to a Paragraph III certification. In so doing, Actavis certified to the FDA that it would not be seeking to sell its generic abiraterone acetate product prior to the December 13, 2016 expiration of the '213 blocking patent.

158. In light of the Paragraph III certification, Actavis, Janssen and BTG all agreed "that a case or controversy no longer exists between them with respect to the '213 patent" and "all

[26] On September 19, 2016, the PTAB accepted Argentum's petition and granted the motion to join the proceeding with the Amerigen action.

claims, counterclaims, and affirmative defenses relating to the '213 patent are dismissed, without prejudice, for lack of subject matter jurisdiction."

159. From this point forward, Janssen and BTG's prosecution of the litigation was solely based on its assertion of the '438 patent which, they both knew, was invalid.

160. By late 2016, the parties in patent litigation over the '438 patent had proceeded to the claim construction phase, wherein the court construes any disputed terms.

161. In a *Markman* decision entered November 10, 2016, Judge McNulty construed the terms "treated" and "treating" as "the eradication, removal, modification, management or control of a tumor or primary, regional, or metastatic cancer cells or tissue and the minimization or delay of the spread of cancer."

162. This was narrower than the PTAB construction of the same terms; the PTAB definition began with the word "include" and thus did not limit the definition to the listed items.

163. On December 13, 2016, the '213 blocking patent expired.

H. The PTAB Grants Additional IPR Petitions.

164. In 2017, the PTAB accepted for *inter partes* review two more petitions challenging all of the claims of the '438 patent. In the meantime, Janssen and BTG continued to pursue litigation against multiple generic manufacturers on the grounds that they were infringing the '438 patent. The FDA began to grant tentative approval to several potential generic competitors.

165. On January 10, 2017, the PTAB determined that Mylan's petition warranted institution of *inter partes* review of claims 1-20 of the '438 patent. The PTAB did not join Mylan's petition with the Amerigen/Argentum proceeding already underway.

166. On April 12, 2017, the PTAB accepted the petition filed by Actavis and others, joining it with the pending Mylan petition.

167. On the litigation front, Janssen and BTG filed an amended complaint on January 30, 2017. The amended complaint reasserted claims relating to the '213 blocking patent, despite that (a) the '213 blocking patent had expired more than a month earlier and (b) Janssen and BTG had agreed almost a year earlier in a stipulation with Actavis that there was no case or controversy as to the '213 blocking patent.

168. Later in the year, on August 25, 2017, Janssen and BTG filed suit against Teva, asserting infringement of the '438 patent in connection with Teva's submission of an ANDA seeking approval to launch a generic version of 500 mg tablets of abiraterone acetate. This case was subsequently consolidated into the pending action before Judge McNulty.

169. Shortly thereafter, in October 2017, at least two generics received tentative approvals from the FDA for their abiraterone acetate ANDAs. Absent the litigation filed by Janssen and BTG, these tentative approvals would have been final approvals.

170. On October 18, 2017, the FDA granted tentative approval to Wockhardt for its abiraterone acetate ANDA, No. 208380.

171. On October 27, 2017, the FDA granted tentative approval to Amneal for its abiraterone acetate ANDA, No. 208327.

172. Both tentative approval letters noted the existence of the Orange Book-listed '438 patent, and the litigation that had been filed by Janssen and BTG, noting that final approval could not be granted until the following occurred: (1) the expiration of the 7.5-year time period provided for in sections 505(j)(5)(B)(iii) and 505(j)(5)(F)(ii) of the FD&C Act; the date the court decides that the '438 patent is invalid or not infringed (see section 505(j)(5)(B)(iii)(I), (II), and (III) of the FD&C Act); or, the '438 patent has expired, and (2) the Agency is assured that there is no new information that would affect whether final approval should be granted.

173. The FDA's letters make clear that both Wockhardt and Amneal were prevented from receiving final approval in October 2017 due to the litigation that Janssen and BTG had filed and were continuing to pursue concerning the '438 patent.

I. The PTAB Issues Three Decisions in 2018 on Invalidity of the '438 Patent.

174. On January 17, 2018, the PTAB issued two final written decisions, one in the Amerigen/Argentum matter and one in the Mylan matter, both concluding that all claims of the '438 patent were invalid. The PTAB's reasoning in these two decisions was substantially similar.

175. The PTAB noted Judge McNulty's claim construction decision, but elected to continue with its initial interpretation of the key claims terms (including the broader definition of "treat"), to which Janssen did not object:

Claim term(s)	**PTAB Construction**
"treat," "treating," and "treatment"	Include the eradication, removal, modification, management or control of a tumor or primary, regional, or metastatic cancer cells or tissue and the minimization or delay of the spread of cancer
"anti-cancer agent"	Any therapeutic agent that directly or indirectly kills cancer cells or directly or indirectly prohibits, stops or reduces the proliferation of cancer cells
"refractory cancer"	Cancer that is not responding to an anti-cancer treatment or cancer that is not responding sufficiently to an anti-cancer treatment
"therapeutically effective amount of prednisone"	An amount of prednisone effective for treating prostate cancer.

176. The PTAB rejected Janssen's argument that POSAs considered the prior art teachings about ketoconazole to be irrelevant to abiraterone, along with Janssen's related suggestion that POSAs were unmotivated to combine abiraterone with a glucocorticoid. Noting that the '438 specification described administering abiraterone with "at least one additional therapeutic agent, such as an anti-cancer agent or a steroid," the PTAB concluded that a POSA

would have reasonably expected success in using prednisone. The specification's defining prednisone as both an "anti-cancer agent" and a "steroid" demonstrated that prednisone was expected to have therapeutic effects even apart from anti-cancer effects.

177. The PTAB began by addressing the generic manufacturers' argument that it was obvious to use a glucocorticoid, such as prednisone, to reduce the undesirable effects of administering a CYP17 inhibitor to reduce testosterone synthesis, including the suppressed production of cortisol, a glucocorticoid, which lead to increased ACTH production.

178. In support, the generic manufacturers cited O'Donnell (2004), which taught, *inter alia*, that abiraterone acetate was more effective than ketoconazole in suppressing testosterone levels, and Gerber (1990), which taught, *inter alia*, that the combination of ketoconazole and prednisone is safe and effective in treating humans with hormone-refractory advanced prostate cancer. The generic manufacturers also cited Barrie (2004) – the '213 blocking patent – which, like O'Donnell (2004), taught, *inter alia*, that abiraterone acetate is more effective than ketoconazole in suppressing testosterone levels in mammals *in vitro*. In light of O'Donnell (2004)/Gerber (1990) and Barrie (2004)/Gerber (1990), it would have been obvious to one skilled in the art to combine abiraterone acetate and prednisone with a reasonable expectation of success.

179. The PTAB rejected each of Janssen's responsive arguments on obviousness.

180. First, the PTAB rejected Janssen's argument that because abiraterone acetate and ketoconazole have different effects on steroid biosynthesis and different side effects, a POSA would not have used the example of ketoconazole's clinical use to take investigative steps with abiraterone acetate. The PTAB, while acknowledging differences in the specific mechanism by which abiraterone acetate and ketoconazole functioned, concluded that "one of ordinary skill in

the art would look to the administration of ketoconazole for guidance on how to administer abiraterone acetate."

181. Second, the PTAB rejected Janssen's argument that O'Donnell (2004) did not establish a need for glucocorticoid replacement with abiraterone acetate, agreeing with the generic manufacturers' "plain reading of O'Donnell (2004) as indicating further investigation of the necessity of co-administration of a glucocorticoid with abiraterone acetate."

182. Third, the PTAB rejected Janssen's argument that ketoconazole plus prednisone was not known to be "safe and effective" for prostate cancer in 2006, noting that Gerber (1990) was a peer-reviewed article published in a reputable journal and O'Donnell (2004) corroborates that the clinical use of ketoconazole is "common practice."

183. Fourth, the PTAB rejected Janssen's argument that prednisone's side effects would have dissuaded a person from using it without a clear clinical benefit, pointing out that while glucocorticoids have certain risks, they did not outweigh the positive effects in seriously ill patients with limited life expectancy.

184. Fifth, the PTAB rejected Janssen's argument that in 2006, prednisone was not known to have anti-cancer effects. Construing the term "therapeutically effective amount of prednisone" as "an amount of prednisone effective for treating prostate cancer" and recognizing that "treating" can include a number of actions, the PTAB concluded that prior art provides a reasonable expectation that prednisone could be used as a therapeutic agent in the treatment of prostate cancer.[27]

[27] This claim construction was broader than the construction adopted by Judge McNulty in his 2016 *Markman* opinion. However, any difference in construction is immaterial to the obviousness analysis. In his final opinion, Judge McNulty noted studies finding glucocorticoids alone may have antitumor effects, and also found the palliative effects of prednisone would have provided some of the motivation to combine it with abiraterone acetate.

185. Sixth, the PTAB rejected Janssen's argument that the prior art provided no basis to expect that prednisone would provide anti-prostate cancer effects, for the same basic reasons it rejected Janssen's fifth argument.

186. Seventh, the PTAB rejected Janssen's contention that the generic manufacturers were relying on hindsight, noting that prior research did focus on use of a CYP17 inhibitor with glucocorticoids to treat prostate cancer.

187. Eighth, the PTAB rejected Janssen's argument that there was no motivation to combine abiraterone acetate with prednisone, finding that none of the prior art taught away from, and instead encouraged, doing exactly that.

188. Next, the PTAB addressed and specifically rejected the four secondary considerations that Janssen posited to overcome the clear obviousness, including the alleged "commercial success" argument that Janssen had presented to PTO examiner Hui.

189. The PTAB found no unexpected results, determining there was insufficient evidence of the allegedly unexpected results and noting that in any event, Janssen failed to tie those results to the administration or abiraterone acetate and prednisone.

190. The PTAB rejected the "skepticism and failure of others" argument noting, among other things, that Janssen's arguments were all directed solely to abiraterone acetate (not the combination of abiraterone acetate and prednisone). The PTAB also noted that abiraterone acetate itself had been previously patented, demonstrating that at least some had overcome any skepticism.

191. The PTAB found that any "long felt need" was, at best, neutral. Of course, any drug that improves cancer patient survival rates will nearly always satisfy a need. But abiraterone acetate's availability for nearly a decade before the issuance of the '438 patent undermined Janssen's argument.

192. Finally, the PTAB turned to the "commercial success" argument – *i.e.*, the specific basis upon which Janssen had first obtained the '438 patent.

193. The PTAB began by noting there was no dispute that Zytiga is commercially successful in term of dollar sales, although it stressed that abiraterone acetate was previously known and patented before the '438 patent issued. The PTAB was persuaded by the generic manufacturers' "argument that the blocking patent would have deterred others from exploring the commercial potential of abiraterone acetate, and thus, that blocking patent to abiraterone acetate limits the applicability of other evidence of commercial success."

194. The PTAB also credited the generic manufacturers' argument that there was no nexus between the commercial success of Zytiga and the claimed invention of the '438 patent, as the record, including Janssen's own prescribing literature, demonstrated that Zytiga's anti-cancer effects come from abiraterone acetate.

195. On the same day that it issued its decision in the Amerigen and Mylan proceedings, the PTAB issued a final written decision in the Wockhardt proceeding. The Wockhardt decision addressed obviousness over the combination of Gerber (1990), O'Donnell (2004) and Sartor (1998), a different combination of prior art than Amerigen and Mylan had relied upon.

196. The PTAB once again found the claims of the '438 patent invalid as obvious. In addition to the O'Donnell (2004) and Gerber (1990) references that the PTAB relied on in the Amerigen/Mylan decision, the PTAB highlighted the Sartor (1998) reference as another, independent basis, for concluding that the claims of the '438 patent were obvious. Sartor (1998), recognized by the PTAB as a peer-reviewed article published in a reputable journal, disclosed that the administration of prednisone alone demonstrated some degree of success in a group of patients,

and indicated some measure of efficacy for certain metastatic castration-resistant prostate cancer patients.

197. As with the Amerigen and Mylan petitions, the PTAB rejected Janssen's non-obviousness arguments as weak and unsupported. In so doing, it reiterated that both abiraterone and prednisone were known in the prior art and that Janssen's assertion that the combination of the two drove Zytiga's sales failed to demonstrate a nexus between commercial success and the claimed invention.

198. On February 16, 2018, Janssen filed a request for rehearing on the petitions.

J. Judge McNulty Found Clear and Convincing Evidence That the '438 Patent Was Invalid.

199. Apotex was the only generic manufacturer named in the Janssen/BTG litigation that had not filed, or joined, any of the PTAB petitions. As such, Apotex possessed something no other generic did at the time: the unquestioned ability to challenge the validity of the '438 patent at the upcoming trial in the district court.

200. Apotex's unique status came from 35 U.S.C. § 315(e)(2), an estoppel provision providing that a party who seeks review of a patent claim before the PTAB that leads to a written decision from the PTAB may not pursue an invalidity argument in the district court on the same grounds that it had presented to the PTAB.

201. It is an open question whether this provision prevents successful PTAB petitioners (such as the non-Apotex generics here) from pursuing an invalidity defense in the district court. Because Apotex had not filed or joined any of the petitions decided by the PTAB, there was no question that Apotex was free to pursue any and all invalidity defenses in the district court.

202. Janssen and BTG settled with Apotex on April 20, 2018, entering into a license agreement for the '438 patent and dismissing Apotex from the action.

203. With Apotex dismissed, Janssen and BTG filed a motion *in limine* based on the language of § 315(e)(2) seeking to prevent the generic defendants from raising at trial the very invalidity defenses on which they had prevailed at the PTAB. Janssen and BTG argued that Judge McNulty must ignore the invalidity determinations of the PTAB and enforce the '438 patent without any examination of its merits.

204. On July 23, 2018, Judge McNulty commenced what would be a nine-day trial, concluding on August 2, 2018. Between August 31, 2018 and September 21, 2018, the parties submitted their post-trial briefings.

205. On October 26, 2018, Judge McNulty issued his opinion, finding, *inter alia*, that the generic defendants had met their burden of proving, by clear and convincing evidence, that the '438 patent is invalid on obviousness grounds.

206. Judge McNulty began his analysis by dispensing with Janssen's argument that the district court lacked subject matter jurisdiction to decide invalidity. While noting that the literal language of 35 U.S.C. § 315(e)(2) could be read in the manner proposed by Janssen, he concluded that doing so would fly in the face of the statute's intent, which is "to prevent parties from using multiple, possibly inconsistent and wasteful means of attacking a patent." Judge McNulty refused to "accept, however, that Congress intended to require a party to stand mute in court because it previously prevailed on the same issue before the PTAB. The result would be a decision reached without consideration of legally relevant facts and issues."

207. Judge McNulty pointed out that "this Court could find itself in the position of being required to enter an injunction against infringement based on a patent already found invalid."

208. As for obviousness, Judge McNulty found, just as examiner Hui and the PTAB had, that the combination therapy claimed in the '438 patent would have been obvious to a POSA. He

noted that abiraterone had been identified in the prior art as a second-line prostate cancer treatment that was regarded as superior to ketoconazole, and that there was more than sufficient motivation to combine abiraterone acetate with prednisone. In fact, the prior art went so far as to identify specific dosages of prednisone (between 10 and 20 mg) to use.

209. The secondary considerations raised by Janssen and BTG did not alter his conclusion on obviousness. Chief among the reasons for this was the fact of the '213 blocking patent. Just like the PTAB had concluded the existence of the '213 blocking patent cast serious doubt on Janssen and BTG's claims of commercial success (and examiner Hui would have reached the same conclusion if she had been informed of the '213 blocking patent), Judge McNulty noted that the sales of Zytiga may not be entirely attributable to the combination therapy claimed in the '438 patent.[28]

210. In his accompanying order, Judge McNulty noted that the 30-month stay (as extended by the NCE exclusivity provision) was set to expire on Sunday, October 28, 2018. Based on his preliminary assessment that the case presented a potentially appealable issue relating to the PTAB estoppel issue, Judge McNulty entered an order for expedited briefing on the appropriateness of a stay pending appeal. Judge McNulty also found that a "very brief" temporary stay to maintain the status quo through October 30, 2018 was warranted and prevented any generic from launching prior to October 31, 2018.

K. Janssen and BTG's Continued Efforts to Delay Generic Competition.

211. Following Judge McNulty's ruling on invalidity, both the Federal Circuit and Supreme Court quickly disposed of Janssen's emergency motions for a stay.

[28] Judge McNulty also assessed the parties' infringement contentions, finding that if the patent had been valid, the generic products would have infringed it.

212. On October 30, 2018, Judge McNulty heard argument on Janssen's motion and briefly extended his temporary injunction until the earlier of November 9, 2018 or the Federal Circuit's ruling on Janssen's request for an injunction pending appeal.

213. On October 31, 2018, the very first day after the 30-month stay expired, the FDA granted final approval to at least four generic manufacturers' abiraterone acetate ANDAs – Apotex, Hikma, Mylan, and Teva. At that point, they remained blocked from launching only by the temporary injunction.

214. On November 1, 2018, Janssen and BTG filed an emergency motion before the Federal Circuit, seeking an injunction pending appeal, arguing that the "most fundamental[]" error committed by Judge McNulty was his decision to actually examine the validity of the '438 patent.

215. On November 20, 2018, the Federal Circuit rejected Janssen's request for injunctive relief, concluding "based on the papers submitted that [Janssen and BTG] have not established that an injunction is warranted here" and denying the motion for an injunction and vacating the temporary injunction. The Federal Circuit also set a merits briefing schedule and invited the Director of the PTO to submit his views on the PTAB estoppel issues.

216. Later that evening, Janssen filed an emergency motion to reinstate the temporary injunction pending a further appeal to the Supreme Court. The Federal Circuit denied this motion the following morning.

217. On November 21, 2018 Janssen and BTG filed an application for injunctive relief pending appeal with the United States Supreme Court. The Supreme Court denied Janssen's request for injunctive relief pending appeal.

218. Immediately following the Federal Circuit's rejection of Janssen's and BTG's emergency motion, generic competition for Zytiga began. On or about November 21, 2018, Mylan

and Teva each launched 250 mg generic abiraterone acetate products. Hikma/West-Ward and Apotex each launched on November 23, 2018. Janssen itself then launched an authorized generic version of Zytiga.

219. On or about January 7, 2019, Amneal launched its generic product and Wockhardt launched its generic product on or about February 27, 2019.

220. The Federal Circuit consolidated Janssen's appeals of the three PTAB decisions and the district court decision. On May 14, 2019, the Federal Circuit upheld the PTAB's decision invalidating the '438 patent. The Federal Circuit dismissed as moot Janssen's appeal of the district court decision and did not address whether a party who was successful in invalidating a patent in an *inter partes* review could repeat its winning arguments in district court.

L. Generic Competition Should Have Begun As Early As December 2016 But No Later Than October 2017, But For Defendants' Anticompetitive Conduct.

221. If Janssen and BTG had not asserted the '438 patent in litigation against their generic competitors, there would have been no 30-month stay on FDA approval for 10 of the 11 first-to-file ANDA applications. Once the '213 blocking patent expired on December 13, 2016, there would have been no "exclusivity" preventing any of the 11 generics from coming on the market.

222. Absent Janssen and BTG's assertion of the '438 patent, generic competition for Zytiga would have begun as early as December 2016, when the '213 patent expired, and no later than October 2017. And once generic competition entered the market, Janssen would have launched an authorized generic (as it did in November of 2018), thereby bringing even more competition to the market and further driving down the cost of those purchasing Zytiga.

223. But for the sham litigation over the ’438 patent, other generic manufacturers might have altered their ANDA activities so as to be in a position to receive final approval in the fall of 2017 around the same time as Mylan, Teva, and others.

VII. DEFENDANTS’ ACTIONS IMPACT INTERSTATE TRADE AND COMMERCE

224. During the relevant time period, the Defendants manufactured, sold, and shipped Zytiga and generic Zytiga across state lines in an uninterrupted flow of interstate commerce.

225. The business activities of Defendants that are the subject of this action were within the flow of, and substantially affected, interstate trade and commerce.

226. Defendants’ conduct, including the marketing and sale of Zytiga has had, and was intended to have, a direct, substantial, and reasonably foreseeable anticompetitive effect upon interstate commerce within the United States. During the relevant time period, the Defendants used various devices to effectuate the illegal acts alleged herein, including the United States mail, interstate and foreign travel, and interstate and foreign wire commerce.

227. The unlawful monopolization in the market for Zytiga as alleged in this Complaint has directly and substantially affected interstate commerce as Defendants deprived Plaintiff and Class Members of the benefits of free and open competition in the purchase of Zytiga within the United States.

228. The effects of Defendants’ anticompetitive conduct were intended to have, and had, a direct, substantial, and reasonably foreseeable effect on interstate commerce within the United States and on import trade and commerce with foreign nations.

VIII. MARKET POWER AND DEFINITION

229. The relevant geographic market is the United States and its territories and possessions.

230. At all relevant times, Janssen has maintained monopoly power over abiraterone acetate: it had the power to raise and/or maintain the price of abiraterone acetate at supra-competitive levels without losing substantial sales.

231. To the extent that Plaintiff and the class are required to prove monopoly power circumstantially by first defining a relevant product market, Plaintiff alleges that the relevant product market is Zytiga and therapeutically equivalent ("AB-rated") abiraterone acetate generics. To the extent proof of monopoly power by defining a relevant product market is required, the plaintiff alleges that the relevant antitrust market is the market for Zytiga and its AB-rated generic equivalents.

232. Through the sale of Zytiga, Janssen has had a one hundred percent (100%) market share in the relevant market at all times.

233. Prior to the late 2018 generic entrants discussed above, there were no generic competitors to Zytiga and there are no other reasonably interchangeable drug products available to prescribing physicians at the dosages at, and for the indications for which, Zytiga is prescribed.

234. Given the nature of the relevant market, Janssen needed to control only Zytiga and therapeutically equivalent generics of Zytiga, and no other products, to maintain the price of Zytiga profitably at supra-competitive levels.

235. Janssen used its market power to maintain premium pricing for Zytiga since the drug's inception. At all times, Janssen sold branded Zytiga well in excess of both marginal cost and of the competitive price, and has enjoyed unusually high profit margins. Zytiga is extremely expensive, with an average monthly wholesale price of approximately $3,000.

236. Only the market entry of a competing, therapeutically equivalent generic version of Zytiga would make Janssen unable to profitably maintain its prices for Zytiga without losing

substantial sales. However, the FDA's approval process for NDAs serves as a significant barrier to new drug entry into this market. The only feasible way for a generic competitor to enter this market requires obtaining a sample of Zytiga, but Janssen has complete control over its distribution.

237. Janssen has used its market power to foreclose or otherwise adversely affect competition in the market for FDA-approved abiraterone acetate drug products by, among other unlawful tactics, preventing potential competitors from obtaining samples and active pharmaceutical ingredient ("API") supplies, which are necessary for formulating a generic version of the drug. This conduct has caused output to be artificially low, raised competitors' costs, and/or kept the market price for FDA-approved abiraterone acetate artificially high.

238. Janssen has had a significant incentive to maintain its monopoly over abiraterone acetate and keep prices artificially high. Zytiga has been a blockbuster drug for Janssen, with sales of the drug accounting for a large majority of the company's revenues. In the first nine months of 2012, Janssen's combined worldwide sales of Zytiga were approximately $1.2 billion. Analysts following Janssen's stock have warned that loss of its monopoly over abiraterone acetate without a follow-up product to take its place could be financially ruinous for the company.

239. Abiraterone acetate does not exhibit significant, positive cross-price elasticity of demand with any other CYP17 inhibitor used for treating prostate cancer, but it would likely exhibit significant, positive cross-price elasticity of demand with AB-rated generic versions of Zytiga.

240. A small but significant, non-transitory increase to the price of Zytiga would not have caused a significant loss of sales.

241. The Defendants had, and exercised, the power to exclude generic competition to brand Zytiga.

242. At all material times, high barriers to entry, including regulatory protections and high costs of entry and expansion, protected branded Zytiga from the forces of price competition.

IX. EFFECTS OF DEFENDANTS' VIOLATIONS OF THE ANTITRUST LAWS

243. Defendants' monopolization had the following anticompetitive effects in the market for Zytiga:

(a) Competition in the market for Zytiga has been reduced or eliminated;

(b) Prices for Zytiga have maintained at supracompetitive levels; and

(c) U.S. purchasers have been deprived of the benefit of price competition in the market for Zytiga.

244. During the Class Period, Plaintiff and Class Members directly purchased Zytiga from Janssen. As a result of the Defendants' anticompetitive conduct, Plaintiff and Class Members paid more for Zytiga than they would have and thus suffered substantial damages. Plaintiff and Class Members have sustained substantial losses and damage to their business and property in the form of overcharges. This is a cognizable antitrust injury and constitutes harm to competition under the federal antitrust laws.

245. The unlawful conduct of Defendants' unlawful conduct deprived Plaintiff and Class Members of the benefits of competition that the antitrust laws were designed to ensure.

246. Defendants' anticompetitive conduct is ongoing, and as a result Plaintiff and Class Members continue to pay supracompetitive prices for Zytiga.

X. CLASS ACTION ALLEGATIONS

247. Pursuant to Federal Rules of Civil Procedure 23(a) and 23(b)(3), Plaintiff brings this action on behalf of a Direct Purchaser Class defined as follows:

> All persons in the United States and its territories that directly purchased Zytiga or abiraterone acetate from December 13, 2016 until the effects of the defendants' conduct cease (the "class").

248. Excluded from the Direct Purchaser Class are Defendants and their officers, directors, management, employees, subsidiaries, or affiliates, and all governmental entities.

249. The class seeks damages for at least the four years preceding the date the complaint is filed.

250. Members of the Class are so numerous that joinder is impracticable. Plaintiff believes that the Class is numerous, geographically dispersed throughout the United States such that joinder of all Class Members is impracticable. Further, the Class is readily identifiable from information and records maintained by Defendants.

251. Plaintiff's claims are typical of the claims of Class Members. Plaintiff's interests are not antagonistic to the claims of the other Class Members, and there are no material conflicts with any other member of the Class that would make class certification inappropriate. Plaintiff and Class Members were damaged by the same wrongful conduct of Defendants.

252. Plaintiff will fairly and adequately protect and represent the interests of the Class. The interests of the Plaintiff are coincident with, and not antagonistic to, those of the Class.

253. Plaintiff is represented by counsel who are experienced and competent in the prosecution of class action litigation, and who have particular experience with class action litigation involving alleged violations of antitrust law.

254. Questions of law and fact common to Class Members predominate over questions that may affect only individual Class Members because Defendants have acted on grounds

generally applicable to the entire Class, thereby determining damages with respect to the Class as a whole is appropriate. Such generally applicable conduct is inherent in Defendants' wrongful conduct.

255. The common legal and factual questions, which do not vary from Class member to Class member and which may be determined without reference to individual circumstances of any Class member, include, but are not limited to, the following:

(a) whether Janssen and BTG unlawfully maintained monopoly power through all or part of its overarching scheme;

(b) whether Janssen and BTG's anticompetitive scheme suppressed generic competition to Zytiga;

(c) as to those parts of Janssen and BTG's challenged conduct for which such justifications may be offered, whether there exist cognizable, non-pretextual procompetitive justifications, which defendants' challenged conduct was the least restrictive means of achieving, that offset the harm to competition in the markets in which abiraterone acetate is sold;

(d) whether direct proof of Janssen and BTG's monopoly power is available, and if available, whether it is sufficient to prove Janssen's monopoly power without the need to also define a relevant market;

(e) to the extent a relevant market or markets must be defined, what that definition is or those definitions are;

(f) determination of a reasonable estimate of the amount of delay the defendants' unlawful monopolistic, unfair and unjust conduct caused;

(g) whether the defendants' scheme, in whole or in part, has substantially affected interstate commerce;

(h) whether the defendants' scheme, in whole or in part, caused antitrust injury to the business or property of Plaintiff and Class Members in the nature of overcharges; and

(i) the quantum of overcharges paid by the class in the aggregate;

256. Class action treatment is a superior method for the fair and efficient adjudication of the controversy. Such treatment will permit a large number of similarly situated persons or entities

to prosecute their common claims in a single forum simultaneously, efficiently, and without the unnecessary duplication of evidence, effort, or expense that numerous individual actions would engender. The benefits of proceeding through the class mechanism, including providing injured persons or entities a method for obtaining redress on claims that could not practicably be pursued individually, substantially outweighs potential difficulties in management of this class action.

257. Plaintiff knows of no special difficulty to be encountered in the maintenance of this action that would preclude its maintenance as a class action.

XI. CLAIMS FOR RELIEF

COUNT 1 – CONSPIRACY TO MONOPOLIZE IN VIOLATION OF SECTION 1 OF THE SHERMAN ACT, 15 U.S.C. § 1

258. Plaintiff incorporates and re-alleges, as though fully set forth herein, each of the paragraphs set forth above.

259. At all relevant times, Janssen has had a one hundred percent (100%) market share in the relevant market for Zytiga and abiraterone acetate. That market power is coupled with strong regulatory and contractual barriers to entry into the market.

260. Through an overarching anticompetitive scheme with BTG, Defendants willfully maintained its monopoly power in the market for Zytiga and abiraterone acetate using restrictive or exclusionary conduct, rather than by means of greater business acumen, and caused injuries to the business and property of Plaintiff and the Class Members.

261. Janssen and BTG's conscious objective was to further market dominance by and through the overarching anticompetitive scheme.

262. As stated more fully above, Janssen and BTG knowingly, willfully, and wrongfully maintained Defendants' monopoly power and harmed competition by asserting the '438 patent in

meritless infringement litigation and delaying entry of generic competition for Zytiga as early as December 2016.

263. To the extent that Defendants are permitted to assert one, there is and was no cognizable, non-pretextual procompetitive justification for Defendants' conduct comprising the anticompetitive scheme that outweighs its harmful effects. Even if there were some conceivable such justification that Defendants were permitted to assert, the scheme is and was broader than necessary to achieve such a purpose.

264. Plaintiff and Class Members have been injured in their business or property by the violation of 15 U.S.C. §§ 1, 2. Plaintiff and Class Members' injury consists of having paid higher prices for their Zytiga and abiraterone acetate requirements than they would have paid in the absence of those violations. Such injury, called "overcharges," is of the type that the antitrust laws were designed to prevent, and it flows from that which makes the defendants' conduct unlawful. KPH, as an assignee of direct purchaser McKesson Corporation, is a proper entity to bring a case concerning this conduct.

265. Plaintiff and Class Members have been injured in their business and property as a result of Defendants' conspiracy in violation of Section 1 of the Sherman Act, 15 U.S.C. § 1.

COUNT 2 – MONOPOLIZATION IN VIOLATION OF SECTION 2 OF THE SHERMAN ACT, 15 U.S.C. § 2

266. Plaintiff incorporates and re-alleges, as though fully set forth herein, each of the paragraphs set forth above.

267. Defendants used willful and exclusionary means as part of an overall scheme described herein to improperly maintain and extend Defendants' monopoly power in the market for abiraterone acetate, as described above. Defendants accomplished this scheme by filing

meritless patent infringement litigations in an attempt to delay generic versions of Zytiga from entering the market.

268. The goal, purpose, and effect of Defendants' scheme was to prevent, delay, and/or minimize the success of the entry of AB-rated generic abiraterone acetate competitors which would have sold generic abiraterone acetate in the United States at prices significantly below Defendants' prices for Zytiga.

269. The goal, purpose, and effect of Defendants' scheme was also to maintain and extend Defendants' monopoly power with respect to abiraterone acetate. Defendants' illegal scheme enabled Defendants to continue charging supra-competitive prices for abiraterone acetate, without a substantial loss of sales, reaping substantial unlawful monopoly profits.

270. Plaintiff and Class Members purchased substantial amounts of Zytiga directly from Janssen.

271. As a result of Defendants' illegal conduct, Plaintiff and Class Members were compelled to pay, and did pay, more than they would have paid for abiraterone acetate absent Defendants' illegal conduct. But for Defendants' illegal conduct, competitors would have begun marketing generic versions of Zytiga well before they actually did.

272. Had manufacturers of generic abiraterone acetate entered the market and lawfully competed with Defendants in a timely fashion, Plaintiff and Class Members would have purchased lower-priced generic abiraterone acetate instead of the higher-priced brand name Zytiga for some or all of their abiraterone acetate requirements, and/or would have paid lower net prices on their remaining Zytiga purchases.

273. As a consequence, Plaintiff and the class have sustained damage to their business and property in the form of overcharges. The injury to Plaintiff and the class are the type of injury antitrust laws were designed to prevent, and the injury flows from Defendants' unlawful conduct

274. Defendants' scheme was in the aggregate an act of monopolization undertaken with the specific intent to monopolize the market for abiraterone acetate in the United States, in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2.

275. Under Section 4 of the Clayton Act, 15 U.S.C. § 15, Plaintiff seeks to recover threefold damages and the costs of suit and reasonable attorneys' fees, for the injuries sustained by Plaintiff and Class Members related to their purchases of abiraterone acetate and resulting from violations by the Defendants of Section 2 of the Sherman Act, 15 U.S.C. § 2.

XII. PRAYER FOR RELIEF

WHEREFORE, Plaintiff and Members of the Direct Purchaser Class pray for relief as set forth below:

A. Certification of the Direct Purchaser Class pursuant to Federal Rule of Civil Procedure 23, and appointment of Plaintiff as Class Representative for the Direct Purchaser Class;

B. Permanent injunctive relief that enjoins Defendants from violating the antitrust laws and requires it to take affirmative steps to dissipate the effects of the violations;

C. That acts alleged herein be adjudged and decreed to be unlawful conspiracy to monopolize in violation of the Sherman Act, 15 U.S.C. § 1;

D. That acts alleged herein be adjudged and decreed to be unlawful monopolization in violation of the Sherman Act, 15 U.S.C. § 2;

E. Enter joint and several judgments against Defendants for the damages sustained by Plaintiff and the Direct Purchaser Class defined herein and for any additional damages, penalties, and other monetary relief provided by applicable law, including treble damages;

F. By awarding Plaintiff and Members of the Direct Purchaser Class pre-judgment and post-judgment interest as provided by law, and that such interest be awarded at the highest legal rate from and after the date of service of the complaint in this action;

G. The costs of this suit, including reasonable attorney fees; and

H. Such other and further relief as the Court deems just and proper.

DEMAND FOR JURY TRIAL

Plaintiff, on behalf of itself and others similarly situated, hereby requests a jury trial, pursuant to Federal Rule of Civil Procedure 38, on any and all claims so triable.

DATED: May 14, 2020

TRIEF & OLK

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